

SBS-IRB Consent Form Requirements October 2003

Consent forms used for human subjects research projects that fall under the jurisdiction of the SBS-IRB are required to include the following sections and elements.

Heading:
Consent Form
[Project Title]
[PI]

- A. Project Description—this section **must** include:
1. Statement that the study involves research and an explanation of the purposes of the research.
 2. A description of all procedures to be followed and the expected duration of the subjects' participation.
 3. Identification of any experimental procedures—this runs the gamut: game-playing, questionnaires, interviews, etc. are all experimental procedures in the context of research. This should outline what *exactly* the subjects will be doing in the experiment.
 4. If subjects will be video or audiotaped, this should be indicated in this section; if they have the option of participating without being taped, this should be noted. If personally identifiable data will be presented and/or if data will be archived, these procedures should be noted here; if subjects can request that their data not be presented publicly or archived, it should be noted here.
- B. Risks and Benefits—this section **must** include:
1. Statement of any reasonably foreseeable risks or discomforts to the subject—including emotional distress or breaches of confidentiality.
 2. A description of any benefits to the subject or to others which may reasonably be expected from the research.
- C. Compensation—This section **should** include
1. A clear statement of compensation that will be provided to subjects and the terms and conditions of this compensation. This includes:
 - a. A monetary amount
 - b. Any conditions that may determine or alter this amount (e.g., the outcome of particular decision-making strategies).
 - c. The terms of payment (or non-payment) for cases in which subjects withdraw before the completion of the study. If payment will be complete, pro-rated, or withheld in these cases, the form should outline the exact conditions.
- D. Confidentiality—This section **must** include

1. A statement describing the extent to which records identifying the subject will remain confidential. This should include:
 - a) A statement of how (or if) any links between personally identifiable information and research data will be managed. This includes all data coding measures.
 - b) A statement of how data will be stored (e.g., under lock and key or on a password-protected computer or encrypted disk).
 - c) A statement of who will have access to coded and/or uncoded data.
 - d) A statement of the final disposition of collected data (e.g., archived, destroyed in X years, etc.)

E. Contacts—This section must include

1. An explanation of whom to contact for pertinent answers about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. These include:
 - a) The name and contact information of the PI and any appropriate research staff
 - b) Contact information (address, phone, and email) for the IRB.

F. Subjects rights—This section must include:

1. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which he or she is otherwise entitled.

G. Signature Lines—Signature lines should be included for the following procedures, if appropriate:

1. Consent to participate in research
2. Consent to video or audiotape
3. Consent to use identifying information in presentations or publications (e.g., names, images, or voice recordings).
4. Consent to publicly archive data